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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/723,042      | 11/26/2003  | Jinchun Xie          | NLP-0202-US         | 7827             |

7590 03/06/2006

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| EXAMINER |
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WINAKUR, ERIC FRANK

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3735

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/723,042 | <b>Applicant(s)</b><br>XIE, JINCHUN |  |
|                              | <b>Examiner</b><br>Eric F. Winakur   | <b>Art Unit</b><br>3735             |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/22/05 &amp; 6/24/05</u> . | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Claim Objections*

1. Claim 2 is objected to because of the following informalities: With regard to claim 2, the claim should end with a period. Appropriate correction is required.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 - 6 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Clarke et al. (USPN 5,222,496 - cited by Applicant). Clarke et al. teach an infrared glucose sensor that includes an illumination source, a detector array, and an analyzer (Figure 1). In regard to claim 1, the fingernail is a suitable location (column 3, lines 55 - 58). In regard to claim 6, a wavelength of 1600 nm is used (column 3, lines 33 - 40). In regard to claim 14, reflection absorption spectroscopy is performed.
4. Claims 1, 5, 8 - 10, 12, 16, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Wach et al. (USPN 6,370,406 - cited by Applicant). Wach et al. teach a method and device that uses light delivery and collection fibers (column 53, lines 9-11) and Stokes-shift Raman analysis (column 52, lines 52-67) on a fingernail (column 54, lines 1-6) to determine chemical concentration (column 2, lines 45-50). In regard to claim 8, laser-Raman spectroscopy is performed (column 52, lines 28-30). In regard to

Art Unit: 3735

claims 9-10 and 16-17, a gel and window in the form of a mating surface is disclosed (column 52, lines 64-67 and column 54, lines 1-6).

5. Claims 1 - 6 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Aldrich (USPN 6,064,898 - cited by Applicant). Aldrich teaches illuminating tissue beneath a nail using an illumination source 22, collecting the radiation using a photodetector 30, and analyzing the collected information using a microprocessor to determine various analytes, such as glucose. (Fig. 1). In regard to claim 6, various wavelengths can be used (column 6, lines 49-57). In regard to claim 11, multivariate regression analysis is used (column 11, lines 10-21 of Aldrich).

6. Claims 1 - 5 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Misner et al. (USPN 6,222,189 - cited by Applicant). Misner et al. teach illuminating tissue below a nail using a light source 20, detecting the light with detector 22, and analyzing the radiation to determine a blood constituent, such as glucose. (Abstract, Fig. 2, and column 1, lines 39-46). In regard to claim 13, pressure is applied. (Abstract, Fig. 2, and claim 1).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 16, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke et al. in view of Wach et al. Clarke et al. teaches a glucose

sensor as described in paragraph 3 above. Further, Clarke et al. teach a laminar structure that includes a film 51 (Fig. 3A), but does not teach windows with coupling gel. Wach et al. teach that windows and gel maximize coupling efficiency (column 52, lines 64-67 and column 54, lines 1-6). Therefore it would have been obvious to one with ordinary skill in the art at the time of the invention to use the windows and gel of Wach et al. in the invention of Clarke et al. since the windows and gel maximize the coupling efficiency.

9. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aldrich as applied to claim 1 above, and further in view of Jobsis (USPN 4,281,645 - cited by Applicant). Aldrich teaches that lasers can be used (column 6, lines 13-17), but does not teach the particular lasers set forth in the claim. Jobsis teaches a CW laser that would fulfill the requirements of providing lasers as set forth by Aldrich. (column 19, lines 25-33). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to use the CW laser of Jobsis in the invention of Aldrich since Aldrich teaches that lasers can be used and Jobsis teaches such lasers.

10. Claims 1 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boppart et al. (USPN 6,485,413 - cited by Applicant) in view of Aldrich. Boppart et al. disclose a method for determining an analyte concentration within a tissue, which comprises operating an OCT imaging system consisting of generating an optical source, directing radiation to the sample, directing radiation to a reference mirror, and processing the returned signals (Fig. 1). Boppart et al. teaches that the method is used to determine solute, gas, and metabolite concentrations in organs, lumens, support

Art Unit: 3735

structures, or free space (column 36, lines 4-39). Boppart et al. teach that any external region of the human body can be analyzed (column 19, lines 11-17). Aldrich teaches that the finger and fingernail are suitable locations (Fig. 1). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to use the invention of Boppart et al. on the finger and fingernail since Boppart et al. teach that any external region of the human body can be analyzed and Aldrich teaches one such external region.

11. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Misner et al. in view of Lepper, Jr. et al. (USPN 5,743,262 - cited by Applicant). Misner et al. teach illuminating tissue below a nail using a light source 20, detecting the light with detector 22, and analyzing the radiation to determine a blood constituent, such as glucose. (Abstract, Fig. 2, and column 1, lines 39-46). In regard to claim 13, pressure is applied. (Abstract, Fig. 2, and claim 1). Misner et al. do not teach means for focusing the beam, but Lepper et al. teach that such focusing is desirable in blood glucose sensor systems (column 6, lines 21 - 23). It would have been obvious to one of ordinary skill in the art at the time of the invention to use focusing means of Lepper et al. in the invention of Misner et al. since such focusing is desirable in blood glucose systems.

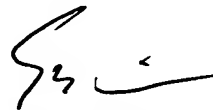
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

Art Unit: 3735

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571/272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eric F Winakur  
Primary Examiner  
Art Unit 3735

2 March 2006